

## Pilot Study Data Evaluation dated Jan 28, 20002

- A. CO
- B. COHb
- C. Acetonitrile in Blood
- D. 3-ABP Hb Adduct
- E. 4-ABP Hb Adduct
- F. Thromboxane
- G. Prostaglandin
- H. Malondialdehyde in Urine
- I. Creatinine
- J. HDL-Cholesterol
- K. LDL-Cholesterol
- L. Fibrinogen
- M. C-Reactive Protein

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TABLE 14.1.1-3  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
OF EXHALATE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL.  
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
Carbon Monoxide (ppm)	Week 1	N	69	68	0.0000
		MEAN, GEO MEAN	24.9, 21.3	5.7, 5.5	
		SD, SE	14.03, 1.69	1.33, 0.16	
		MEDIAN	22.7	5.7	
		MIN, MAX	6.8, 71.4	3.6, 9.6	
		5%, 95%	8.4, 50.4	3.7, 8.1	
	Week 2	N	69	68	0.0000
		MEAN, GEO MEAN	23.8, 20.1	5.2, 4.8	
		SD, SE	14.43, 1.74	1.73, 0.21	
		MEDIAN	21.2	5.2	
		MIN, MAX	4.5, 88.9	0.1, 10.9	
		5%, 95%	6.8, 50.1	3.2, 8.5	
	Week 3	N	68	67	0.0000
		MEAN, GEO MEAN	25.9, 21.6	5.2, 4.9	
		SD, SE	14.90, 1.81	1.63, 0.20	
		MEDIAN	23.7	5.2	
		MIN, MAX	5.3, 65.4	0.3, 10.6	
		5%, 95%	6.3, 55.1	3.2, 8.3	
	Week 6	N	68	67	0.0000
		MEAN, GEO MEAN	26.6, 22.3	6.2, 5.7	
		SD, SE	14.24, 1.73	2.41, 0.29	
		MEDIAN	25.1	5.8	
		MIN, MAX	4.0, 70.5	0.4, 13.8	
		5%, 95%	5.5, 51.1	3.6, 11.6	
	Overall	N	274	270	0.0000
		MEAN, GEO MEAN	25.3, 21.3	5.6, 5.2	
		SD, SE	14.36, 0.87	1.85, 0.11	
		MEDIAN	23.2	5.5	
		MIN, MAX	4.0, 88.9	0.1, 13.8	
		5%, 95%	6.8, 51.2	3.2, 8.8	

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TABLE 14.1.4-3  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER  
OF EXHALATE BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL  
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Biomarker	Timepoint	Statistic	Smokers			Non-Smokers		
			Male	Female	P-value*	Male	Female	P-value*
Carbon Monoxide (ppm)	Week 1	N	30	39	0.6498	32	36	0.1284
		MEAN, GEO MEAN	23.9, 20.5	25.7, 22.0		5.9, 5.8	5.5, 5.3	
		SD, SE	13.75, 2.51	14.38, 2.30		1.30, 0.23	1.34, 0.22	
		MEDIAN	22.4	22.7		5.9	5.4	
		MIN, MAX	6.8, 71.4	7.8, 66.5		3.6, 9.1	3.7, 9.6	
		5%, 95%	7.8, 47.2	8.4, 54.7		3.7, 8.0	4.0, 8.1	
	Week 2	N	30	39	0.2169	32	36	0.0000
		MEAN, GEO MEAN	20.8, 18.1	26.1, 21.7		6.1, 5.4	4.5, 4.3	
		SD, SE	10.44, 1.91	16.64, 2.66		1.83, 0.32	1.28, 0.21	
		MEDIAN	19.5	22.5		6.0	4.4	
		MIN, MAX	4.5, 44.1	6.5, 88.9		0.1, 10.9	2.1, 8.6	
		5%, 95%	6.8, 44.1	6.7, 55.6		4.0, 9.6	2.2, 6.8	
	Week 3	N	30	38	0.4114	31	36	0.0000
		MEAN, GEO MEAN	24.8, 20.2	26.7, 22.7		6.1, 5.9	4.5, 4.2	
		SD, SE	16.10, 2.94	14.04, 2.28		1.53, 0.28	1.31, 0.22	
		MEDIAN	22.7	25.0		6.0	4.5	
		MIN, MAX	5.3, 65.4	5.3, 60.7		3.4, 10.6	0.3, 7.4	
		5%, 95%	6.3, 62.2	7.0, 50.7		4.0, 9.4	3.0, 6.9	
	Week 6	N	30	38	0.2214	31	36	0.0002
		MEAN, GEO MEAN	24.6, 20.7	28.2, 23.8		7.4, 7.1	5.3, 4.7	
		SD, SE	14.13, 2.58	14.31, 2.32		2.41, 0.43	1.98, 0.33	
		MEDIAN	24.4	27.9		7.0	5.2	
		MIN, MAX	5.0, 70.5	4.0, 54.0		4.5, 13.8	0.4, 9.8	
		5%, 95%	5.5, 46.4	5.5, 53.7		4.8, 13.3	1.0, 9.0	
	Overall	N	120	154	0.0640	126	144	0.0000
		MEAN, GEO MEAN	23.5, 19.8	26.7, 22.5		6.4, 6.0	4.9, 4.6	
		SD, SE	13.68, 1.25	14.77, 1.19		1.88, 0.17	1.55, 0.13	
		MEDIAN	22.8	24.5		6.0	4.8	
		MIN, MAX	4.5, 71.4	4.0, 88.9		0.1, 13.8	0.3, 9.8	
		5%, 95%	6.6, 49.2	7.2, 53.2		4.0, 9.6	3.1, 7.4	

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TABLE 14.1.1-1  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL  
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
Carboxyhemoglobin (% saturation)	Week 1	N	68	27	0.0000
		MEAN, GEO MEAN	4.2, 3.2	0.5, 0.5	
		SD, SE	2.89, 0.35	0.19, 0.04	
		MEDIAN	3.4	0.5	
		MIN, MAX	0.3, 14.8	0.3, 1.0	
		5%, 95%	0.9, 8.9	0.3, 0.8	
	Week 2	N	66	20	0.0000
		MEAN, GEO MEAN	4.1, 3.1	0.5, 0.5	
		SD, SE	2.74, 0.34	0.22, 0.05	
		MEDIAN	3.6	0.5	
		MIN, MAX	0.4, 13.3	0.3, 1.1	
		5%, 95%	0.6, 9.1	0.3, 1.0	
	Week 3	N	67	28	0.0000
		MEAN, GEO MEAN	4.6, 3.6	0.8, 0.6	
		SD, SE	2.99, 0.37	0.68, 0.13	
		MEDIAN	3.9	0.5	
		MIN, MAX	0.3, 11.3	0.3, 2.8	
		5%, 95%	0.7, 10.4	0.3, 2.5	
	Week 6	N	64	33	0.0000
		MEAN, GEO MEAN	4.3, 3.4	0.5, 0.5	
		SD, SE	2.70, 0.34	0.26, 0.05	
		MEDIAN	4.1	0.5	
		MIN, MAX	0.3, 13.9	0.3, 1.3	
		5%, 95%	0.8, 8.9	0.3, 1.1	
	Overall	N	265	108	0.0000
		MEAN, GEO MEAN	4.3, 3.3	0.6, 0.5	
		SD, SE	2.82, 0.17	0.41, 0.04	
		MEDIAN	3.9	0.5	
		MIN, MAX	0.3, 14.8	0.3, 2.8	
		5%, 95%	0.7, 9.7	0.3, 1.1	

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TABLE 14.1.4-1  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER  
OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL  
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Biomarker	Timepoint	Statistic	Smokers		P-value <sup>a</sup>	Non-Smokers		P-value <sup>a</sup>
			Male	Female		Male	Female	
Carboxyhemoglobin (% saturation)	Week 1	N	29	39	0.7329	19	8	0.0118
		MEAN, GEO MEAN	4.0, 3.0	4.3, 3.3		0.6, 0.6	0.4, 0.4	
		SD, SE	2.87, 0.53	2.94, 0.47		0.18, 0.04	0.14, 0.05	
		MEDIAN	3.4	3.4		0.5	0.4	
		MIN, MAX	0.3, 14.8	0.8, 11.4		0.3, 1.0	0.3, 0.7	
		5%, 95%	0.4, 7.9	0.9, 11.3		0.3, 1.0	0.3, 0.7	
	Week 2	N	29	37	0.1442	14	6	0.2922
		MEAN, GEO MEAN	3.5, 2.8	4.5, 3.5		0.6, 0.5	0.4, 0.4	
		SD, SE	2.24, 0.42	3.03, 0.50		0.25, 0.07	0.08, 0.03	
		MEDIAN	3.3	4.7		0.5	0.4	
		MIN, MAX	0.4, 8.6	0.4, 13.3		0.3, 1.1	0.3, 0.5	
		5%, 95%	0.5, 8.4	0.6, 10.1		0.3, 1.1	0.3, 0.5	
	Week 3	N	29	38	0.4552	14	14	0.8158
		MEAN, GEO MEAN	4.4, 3.4	4.8, 3.7		0.7, 0.6	0.8, 0.6	
		SD, SE	3.15, 0.59	2.89, 0.47		0.63, 0.17	0.74, 0.20	
		MEDIAN	3.5	4.3		0.5	0.4	
		MIN, MAX	0.6, 11.3	0.3, 9.8		0.3, 2.8	0.3, 2.5	
		5%, 95%	0.7, 11.3	0.5, 9.7		0.3, 2.8	0.3, 2.5	
	Week 6	N	28	36	0.1961	19	14	0.4040
		MEAN, GEO MEAN	4.0, 3.0	4.6, 3.7		0.6, 0.5	0.5, 0.5	
		SD, SE	2.81, 0.53	2.61, 0.43		0.25, 0.06	0.29, 0.08	
		MEDIAN	4.0	4.5		0.5	0.4	
		MIN, MAX	0.3, 13.9	0.4, 9.8		0.3, 1.1	0.3, 1.3	
		5%, 95%	0.4, 8.3	0.8, 9.2		0.3, 1.1	0.3, 1.3	
	Overall	N	115	150	0.0507	66	42	0.0299
		MEAN, GEO MEAN	4.0, 3.0	4.6, 3.5		0.6, 0.5	0.6, 0.5	
		SD, SE	2.77, 0.26	2.85, 0.23		0.35, 0.04	0.49, 0.07	
		MEDIAN	3.6	4.3		0.5	0.4	
		MIN, MAX	0.3, 14.8	0.3, 13.3		0.3, 2.8	0.3, 2.5	
		5%, 95%	0.5, 10.4	0.8, 9.7		0.3, 1.1	0.3, 1.6	

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TABLE 14.1.1-1  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL  
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
Acetonitrile (ng/mL)	Week 1	N	57	52	0.0000
		MEAN, GEO MEAN	306.02, 224.95	214.62, 130.14	
		SD, SE	300.672, 39.825	312.770, 43.373	
		MEDIAN	201.63	100.32	
		MIN, MAX	66.48, 1508.01	33.71, 1521.61	
		5%, 95%	80.8, 1004.3	44.4, 972.7	
	Week 2	N	58	53	0.0010
		MEAN, GEO MEAN	357.86, 260.25	209.85, 151.38	
		SD, SE	326.969, 42.933	180.771, 24.831	
		MEDIAN	265.80	117.58	
		MIN, MAX	48.66, 1701.68	32.17, 756.74	
		5%, 95%	78.7, 1003.0	39.2, 664.0	
	Week 3	N	57	56	0.0006
		MEAN, GEO MEAN	503.17, 299.24	222.63, 163.70	
		SD, SE	639.934, 84.761	205.632, 27.479	
		MEDIAN	243.87	135.72	
		MIN, MAX	46.59, 2679.33	42.35, 1168.91	
		5%, 95%	76.5, 2334.0	55.0, 619.9	
	Week 6	N	57	53	0.0037
		MEAN, GEO MEAN	471.72, 320.42	275.98, 192.48	
		SD, SE	421.643, 55.848	238.629, 32.778	
		MEDIAN	363.52	159.17	
		MIN, MAX	31.69, 1665.36	44.70, 947.37	
		5%, 95%	56.4, 1460.6	62.1, 744.4	
	Overall	N	229	214	0.0000
		MEAN, GEO MEAN	409.47, 273.66	230.73, 158.07	
		SD, SE	446.874, 29.530	238.579, 16.309	
		MEDIAN	242.43	125.55	
		MIN, MAX	31.69, 2679.33	32.17, 1521.61	
		5%, 95%	80.8, 1406.4	47.2, 688.4	

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TABLE 14.1.4-1  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER  
OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL  
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Biomarker	Timepoint	Statistic	Smokers		P-value*	Non-Smokers		P-value*
			Male	Female		Male	Female	
Acetonitrile (ng/mL)	Week 1	N	18	39	0.0003	24	28	0.2438
		MEAN, GEO MEAN	502.04, 390.23	215.56, 174.45		202.37, 139.86	225.11, 122.34	
		SD, SE	350.343, 82.577	227.415, 36.416		279.883, 57.131	343.226, 64.864	
		MEDIAN	423.35	172.48		113.18	91.43	
		MIN, MAX	132.35, 1346.61	66.48, 1508.01		53.62, 1436.85	33.71, 1521.61	
		5%, 95%	132.4, 1346.6	75.2, 386.2		65.0, 431.1	43.9, 972.7	
	Week 2	N	20	38	0.1182	23	30	0.6344
		MEAN, GEO MEAN	426.13, 324.25	321.94, 231.82		197.48, 158.15	219.34, 146.39	
		SD, SE	349.525, 78.156	313.237, 50.814		144.658, 30.163	206.170, 37.641	
		MEDIAN	335.60	206.97		168.34	112.20	
		MIN, MAX	96.28, 1578.50	48.66, 1701.68		46.04, 688.37	32.17, 756.74	
		5%, 95%	99.6, 1195.2	60.9, 1003.0		69.2, 371.9	36.3, 664.0	
	Week 3	N	19	38	0.0013	24	32	0.0334
		MEAN, GEO MEAN	830.20, 527.59	339.65, 225.36		254.59, 202.98	198.66, 139.32	
		SD, SE	854.396, 196.012	426.961, 69.262		174.733, 35.667	225.799, 39.916	
		MEDIAN	429.35	213.44		203.55	114.16	
		MIN, MAX	133.94, 2679.33	46.59, 2333.96		54.99, 722.48	42.35, 1168.91	
		5%, 95%	133.9, 2679.3	68.0, 1389.4		59.4, 568.7	44.4, 619.9	
	Week 6	N	20	37	0.0600	24	29	0.2797
		MEAN, GEO MEAN	488.78, 408.12	462.50, 281.14		241.98, 167.68	304.13, 215.75	
		SD, SE	252.496, 56.460	492.600, 80.983		234.668, 47.901	242.294, 44.993	
		MEDIAN	482.10	254.94		122.41	193.47	
		MIN, MAX	31.69, 1060.80	49.12, 1665.36		52.97, 886.61	44.70, 947.37	
		5%, 95%	118.7, 1043.6	56.4, 1614.8		66.5, 744.4	62.1, 670.9	
	Overall	N	77	152	0.0000	95	119	0.2407
		MEAN, GEO MEAN	559.85, 405.32	333.29, 224.28		224.38, 165.73	235.80, 152.21	
		SD, SE	521.467, 59.427	383.784, 31.129		213.593, 21.914	257.572, 23.612	
		MEDIAN	406.11	194.92		138.68	112.74	
		MIN, MAX	31.69, 2679.33	46.59, 2333.96		46.04, 1436.85	32.17, 1521.61	
		5%, 95%	107.7, 2035.8	75.2, 1389.4		59.4, 688.4	43.9, 756.7	

TABLE 14.1.1-1  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL  
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
Acetonitrile (nmol/L)	Week 1	N	57	52	0.0000
		MEAN, GEO MEAN	7460.9, 5484.2	5232.3, 3172.7	
		SD, SE	7330.39, 970.93	7625.34, 1057.45	
		MEDIAN	4915.7	2445.8	
		MIN, MAX	1620.8, 36765.3	821.8, 37096.9	
		5%, 95%	1969.7, 24485.6	1083.2, 23713.9	
	Week 2	N	58	53	0.0010
		MEAN, GEO MEAN	8724.8, 6345.0	5116.2, 3690.8	
		SD, SE	7971.50, 1046.71	4407.20, 605.38	
		MEDIAN	6480.1	2866.6	
		MIN, MAX	1186.3, 41487.0	784.3, 18449.3	
		5%, 95%	1917.7, 24452.2	956.2, 16188.6	
	Week 3	N	57	56	0.0006
		MEAN, GEO MEAN	12267.3, 7295.4	5427.7, 3991.1	
		SD, SE	15601.59, 2066.48	5013.31, 669.93	
		MEDIAN	5945.6	3308.9	
		MIN, MAX	1135.9, 65322.1	1032.5, 28498.0	
		5%, 95%	1864.8, 56901.9	1340.7, 15114.1	
	Week 6	N	57	53	0.0037
		MEAN, GEO MEAN	11500.5, 7811.8	6728.5, 4692.6	
		SD, SE	10279.67, 1361.58	5817.78, 799.13	
		MEDIAN	8862.6	3880.6	
		MIN, MAX	772.6, 40601.5	1089.8, 23096.9	
		5%, 95%	1376.0, 35608.5	1512.8, 18147.3	
	Overall	N	229	214	0.0000
		MEAN, GEO MEAN	9982.8, 6671.8	5625.2, 3853.7	
		SD, SE	10894.80, 719.95	5816.55, 397.61	
		MEDIAN	5910.4	3060.9	
		MIN, MAX	772.6, 65322.1	784.3, 37096.9	
		5%, 95%	1969.7, 34287.5	1150.7, 16782.5	

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TABLE 14.1.4-1  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER  
OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL  
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Biomarker	Timepoint	Statistic	Smokers		P-value <sup>a</sup>	Non-Smokers		P-value <sup>a</sup>
			Male	Female		Male	Female	
Acetonitrile (nmol/L)	Week 1	N	18	39	0.0003	24	28	0.2438
		MEAN, GEO MEAN	12239.6, 9513.7	5255.3, 4253.0		4933.7, 3409.8	5488.2, 2982.7	
		SD, SE	8541.38, 2013.22	5544.38, 887.81		6823.56, 1392.85	8367.85, 1581.38	
		MEDIAN	10321.2	4205.1		2759.2	2229.1	
		MIN, MAX	3226.7, 32830.4	1620.8, 36765.3		1307.3, 35030.4	821.8, 37096.9	
		5%, 95%	3226.7, 32830.4	1832.4, 9415.6		1585.4, 10510.9	1070.8, 23713.9	
	Week 2	N	20	38	0.1182	23	30	0.6344
		MEAN, GEO MEAN	10389.0, 7905.2	7848.8, 5651.7		4814.5, 3855.8	5347.6, 3569.1	
		SD, SE	8521.43, 1905.45	7636.73, 1238.84		3526.75, 735.38	5026.42, 917.69	
		MEDIAN	8181.8	5046.0		4104.1	2735.5	
		MIN, MAX	2347.3, 38483.8	1186.3, 41487.0		1122.5, 16782.5	784.3, 18449.3	
		5%, 95%	2427.4, 29140.1	1485.5, 24452.2		1687.1, 9065.9	884.3, 16188.6	
	Week 3	N	19	38	0.0013	24	32	0.0334
		MEAN, GEO MEAN	20240.3, 12862.6	8280.8, 5494.3		6206.8, 4948.7	4843.4, 3396.6	
		SD, SE	20830.16, 4778.77	10409.32, 1688.61		4260.00, 869.57	5504.96, 973.15	
		MEDIAN	10467.6	5203.7		4962.5	2783.2	
		MIN, MAX	3265.5, 65322.1	1135.9, 56901.9		1340.7, 17614.1	1032.5, 28498.0	
		5%, 95%	3265.5, 65322.1	1657.1, 33872.4		1448.9, 13864.7	1082.0, 15114.1	
	Week 6	N	20	37	0.0600	24	29	0.2797
		MEAN, GEO MEAN	11916.4, 9949.9	11275.7, 6854.3		5899.5, 4088.1	7414.6, 5260.0	
		SD, SE	6155.86, 1376.49	12009.58, 1974.36		5721.21, 1167.84	5907.12, 1096.92	
		MEDIAN	11753.6	6215.4		2984.2	4716.8	
		MIN, MAX	772.6, 25862.3	1197.5, 40601.5		1291.4, 21615.6	1089.8, 23096.9	
		5%, 95%	2894.8, 25442.0	1376.0, 39367.6		1621.5, 18147.3	1512.8, 16357.0	
	Overall	N	77	152	0.0000	95	119	0.2407
		MEAN, GEO MEAN	13649.2, 9881.8	8125.5, 5467.9		5470.5, 4040.4	5748.8, 3710.9	
		SD, SE	12713.35, 1448.82	9356.66, 758.93		5207.41, 534.27	6279.62, 575.65	
		MEDIAN	9901.0	4752.2		3381.0	2748.6	
		MIN, MAX	772.6, 65322.1	1135.9, 56901.9		1122.5, 35030.4	784.3, 37096.9	
		5%, 95%	2626.2, 49631.8	1832.4, 33872.4		1448.9, 16782.5	1070.8, 18449.3	

**D**

PM3006635366

JAN 28 2002

TABLE 14.1.1-1  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL  
 (Page 4 of 7)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
Hb adduct of 3-aminobiphenyl (pg/g hemoglobin)	Week 1	N	64	13	0.0000
		MEAN, GEO MEAN	3.75, 2.77	0.99, 0.78	
		SD, SE	3.219, 0.402	1.093, 0.303	
		MEDIAN	2.55	0.62	
		MIN, MAX	0.86, 15.03	0.51, 4.59	
		5%, 95%	0.9, 10.4	0.5, 4.6	
	Week 6	N	62	6	0.0290
		MEAN, GEO MEAN	5.08, 3.10	1.52, 1.44	
		SD, SE	8.305, 1.055	0.555, 0.227	
		MEDIAN	2.73	1.40	
		MIN, MAX	0.77, 63.34	1.00, 2.46	
		5%, 95%	1.1, 12.7	1.0, 2.5	
	Overall	N	126	19	0.0000
		MEAN, GEO MEAN	4.41, 2.93	1.16, 0.95	
		SD, SE	6.271, 0.559	0.973, 0.223	
		MEDIAN	2.57	0.88	
		MIN, MAX	0.77, 63.34	0.51, 4.59	
		5%, 95%	1.0, 12.3	0.5, 4.6	

JAN 28 2002

TABLE 14.1.4-1  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER  
OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL  
(Page 4 of 7)

Biomarker	Timepoint	Statistic	Smokers		P-value <sup>a</sup>	Non-Smokers		P-value <sup>a</sup>
			Male	Female		Male	Female	
Hb adduct of 3-aminobiphenyl (pg/g hemoglobin)	Week 1	N	27	37	0.5184	4	9	0.3159
		MEAN, GEO MEAN	4.41, 3.05	3.27, 2.58		0.64, 0.62	1.14, 0.86	
		SD, SE	3.978, 0.766	2.479, 0.407		0.175, 0.088	1.301, 0.434	
		MEDIAN	2.74	2.27		0.58	0.72	
		MIN, MAX	0.86, 15.03	0.95, 10.41		0.51, 0.89	0.55, 4.59	
		5%, 95%	0.9, 14.0	1.0, 9.4		0.5, 0.9	0.6, 4.6	
	Week 6	N	27	35	0.7819	2	4	0.4875
		MEAN, GEO MEAN	4.34, 3.13	5.65, 3.09		1.91, 1.82	1.33, 1.28	
		SD, SE	3.612, 0.695	10.630, 1.797		0.785, 0.555	0.400, 0.200	
		MEDIAN	2.68	2.78		1.91	1.24	
		MIN, MAX	0.77, 12.65	0.81, 63.34		1.35, 2.46	1.00, 1.84	
		5%, 95%	1.1, 12.3	1.0, 14.2		1.4, 2.5	1.0, 1.8	
	Overall	N	54	72	0.4793	6	13	0.6295
		MEAN, GEO MEAN	4.38, 3.09	4.43, 2.81		1.06, 0.89	1.20, 0.97	
		SD, SE	3.764, 0.512	7.659, 0.903		0.755, 0.308	1.084, 0.301	
		MEDIAN	2.73	2.29		0.76	0.88	
		MIN, MAX	0.77, 15.03	0.81, 63.34		0.51, 2.46	0.55, 4.59	
		5%, 95%	0.9, 12.7	1.0, 10.4		0.5, 2.5	0.6, 4.6	

**E**

PM3006635369



TABLE 14.1.1-1  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL  
 (Page 5 of 7)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
Hb adduct of 4-aminobiphenyl (pg/g hemoglobin)	Week 1	N	68	68	0.0000
		MEAN, GEO MEAN	34.22, 28.74	7.84, 6.79	
		SD, SE	20.570, 2.495	4.911, 0.596	
		MEDIAN	29.84	6.76	
		MIN, MAX	5.35, 100.50	2.49, 29.69	
		5%, 95%	11.4, 79.9	3.1, 17.4	
	Week 6	N	68	67	0.0000
		MEAN, GEO MEAN	50.52, 35.24	9.31, 8.19	
		SD, SE	95.529, 11.585	5.934, 0.725	
		MEDIAN	36.86	7.53	
		MIN, MAX	7.27, 808.80	4.09, 40.55	
		5%, 95%	11.4, 81.7	4.4, 20.6	
	Overall	N	136	135	0.0000
		MEAN, GEO MEAN	42.37, 31.82	8.57, 7.45	
		SD, SE	69.326, 5.945	5.473, 0.471	
		MEDIAN	32.68	7.12	
		MIN, MAX	5.35, 808.80	2.49, 40.55	
		5%, 95%	11.4, 81.7	3.4, 20.6	

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TABLE 14.1.4-1  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER  
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EXPOSURE BY TIMEPOINT AND OVERALL  
 (Page 5 of 7)

Biomarker	Timepoint	Statistic	Smokers			Non-Smokers		
			Male	Female	P-value <sup>a</sup>	Male	Female	P-value <sup>a</sup>
Hb adduct of 4-aminobiphenyl (pg/g hemoglobin)	Week 1	N	30	38	0.0234	32	36	0.1307
		MEAN, GEO MEAN	42.28, 35.41	27.86, 24.38		7.54, 6.23	8.10, 7.33	
		SD, SE	25.024, 4.569	13.462, 2.184		5.813, 1.028	4.012, 0.669	
		MEDIAN	38.12	26.66		5.50	6.82	
		MIN, MAX	12.37, 100.50	5.35, 67.83		2.90, 29.69	2.49, 23.25	
		5%, 95%	12.8, 90.7	5.4, 50.5		3.1, 23.2	3.0, 17.4	
	Week 6	N	30	38	0.5247	31	36	0.8801
		MEAN, GEO MEAN	38.60, 32.72	59.93, 37.36		9.94, 8.29	8.76, 8.10	
		SD, SE	21.692, 3.960	126.294, 20.488		7.700, 1.383	3.862, 0.644	
		MEDIAN	36.58	37.63		7.50	7.94	
		MIN, MAX	9.56, 97.75	7.27, 808.80		4.11, 40.55	4.09, 22.67	
		5%, 95%	11.4, 74.6	7.3, 90.3		4.3, 27.9	4.4, 15.9	
	Overall	N	60	76	0.2206	63	72	0.2096
		MEAN, GEO MEAN	40.44, 34.04	43.90, 30.18		8.72, 7.17	8.43, 7.71	
		SD, SE	23.292, 3.007	90.657, 10.399		6.859, 0.864	3.924, 0.462	
		MEDIAN	36.58	31.50		7.06	7.32	
		MIN, MAX	9.56, 100.50	5.35, 808.80		2.90, 40.55	2.49, 23.25	
		5%, 95%	12.1, 89.0	7.3, 74.9		3.2, 23.2	4.1, 15.9	

**F**

PM3006635372

JAN 28 2002

TABLE 14.2.1-2  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
(Page 5 of 7)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
11-Dehydrothromboxane B <sub>2</sub> (pg/mg Creatinin)	Week 1	N	59	55	0.0003
		MEAN, GEO MEAN	985.368, 893.189	705.622, 658.489	
		SD, SE	437.6925, 56.9827	246.5333, 33.2425	
		MEDIAN	931.937	716.848	
		MIN, MAX	345.794, 2284.404	227.688, 1314.159	
		5%, 95%	405.1, 1799.4	267.9, 1150.0	
	Week 2	N	64	56	0.0072
		MEAN, GEO MEAN	1024.565, 924.518	790.034, 731.443	
		SD, SE	471.5304, 58.9413	310.4590, 41.4868	
		MEDIAN	916.502	762.028	
		MIN, MAX	250.508, 2312.883	261.458, 1988.571	
		5%, 95%	457.5, 2121.5	296.0, 1266.4	
	Week 3	N	60	50	0.0031
		MEAN, GEO MEAN	1059.358, 955.688	805.378, 759.735	
		SD, SE	487.2286, 62.9009	252.4852, 35.7068	
		MEDIAN	1001.278	762.784	
		MIN, MAX	333.333, 2422.550	203.209, 1393.314	
		5%, 95%	394.6, 2078.3	436.9, 1266.3	
	Overall	N	183	161	0.0000
		MEAN, GEO MEAN	1023.335, 924.293	765.963, 714.021	
		SD, SE	464.6157, 34.3454	274.0584, 21.5988	
		MEDIAN	929.912	756.454	
		MIN, MAX	250.508, 2422.550	203.209, 1988.571	
		5%, 95%	416.1, 1962.0	296.0, 1239.7	

JAN 28 2002

TABLE 14.2.1-2  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
 (Page 6 of 7)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
11-Dehydrothromboxane B <sub>2</sub> (pmol/mg Creatin)	Week 1	N	59	55	0.0003
		MEAN, GEO MEAN	2.670, 2.421	1.912, 1.784	
		SD, SE	1.1862, 0.1544	0.6681, 0.0901	
		MEDIAN	2.526	1.943	
		MIN, MAX	0.937, 6.191	0.617, 3.561	
		5%, 95%	1.1, 4.9	0.7, 3.1	
	Week 2	N	64	56	0.0072
		MEAN, GEO MEAN	2.777, 2.505	2.141, 1.982	
		SD, SE	1.2778, 0.1597	0.8413, 0.1124	
		MEDIAN	2.484	2.065	
		MIN, MAX	0.679, 6.268	0.709, 5.389	
		5%, 95%	1.2, 5.7	0.8, 3.4	
	Week 3	N	60	50	0.0031
		MEAN, GEO MEAN	2.871, 2.590	2.183, 2.059	
		SD, SE	1.3204, 0.1705	0.6842, 0.0968	
		MEDIAN	2.714	2.067	
		MIN, MAX	0.903, 6.565	0.551, 3.776	
		5%, 95%	1.1, 5.6	1.2, 3.4	
	Overall	N	183	161	0.0000
		MEAN, GEO MEAN	2.773, 2.505	2.076, 1.935	
		SD, SE	1.2591, 0.0931	0.7427, 0.0585	
		MEDIAN	2.520	2.050	
		MIN, MAX	0.679, 6.565	0.551, 5.389	
		5%, 95%	1.1, 5.3	0.8, 3.4	

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TABLE 14.2.1-2  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
 (Page 1 of 7)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
11-Dehydrothromboxane B <sub>2</sub> (pg/mL)	Week 1	N	59	55	0.1639
		MEAN, GEO MEAN	844.5, 687.0	672.7, 573.2	
		SD, SE	658.82, 85.77	397.87, 53.65	
		MEDIAN	684.0	594.0	
		MIN, MAX	222.0, 3636.0	246.0, 1758.0	
	Week 2	5%, 95%	243.0, 2281.0	248.0, 1572.0	0.0545
		N	64	56	
		MEAN, GEO MEAN	1011.7, 809.2	817.9, 647.5	
		SD, SE	708.09, 88.51	691.63, 92.42	
		MEDIAN	775.5	646.0	
	Week 3	MIN, MAX	222.0, 3362.0	228.0, 4070.0	0.2053
		5%, 95%	271.0, 2717.0	260.0, 2036.0	
		N	60	50	
		MEAN, GEO MEAN	869.5, 735.1	740.0, 633.7	
		SD, SE	541.28, 69.88	423.67, 59.92	
	Overall	MEDIAN	693.0	634.0	0.0067
		MIN, MAX	236.0, 2876.0	228.0, 1904.0	
		5%, 95%	264.5, 1978.5	262.0, 1567.0	
		N	183	161	
		MEAN, GEO MEAN	911.1, 743.8	744.1, 617.0	
		SD, SE	642.20, 47.47	525.82, 41.44	
		MEDIAN	720.0	603.0	
		MIN, MAX	222.0, 3636.0	228.0, 4070.0	
		5%, 95%	256.0, 2168.0	256.0, 1600.0	

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TABLE 14.2.I-2  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
 (Page 2 of 2)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value*
11-Dehydrothromboxane B <sub>2</sub> (pmol/L)	Week 1	N	59	55	0.1639
		MEAN, GEO MEAN	2288.5, 1861.8	1823.0, 1553.4	
		SD, SE	1785.40, 232.44	1078.22, 145.39	
		MEDIAN	1853.6	1609.7	
		MIN, MAX	601.6, 9853.6	666.7, 4764.2	
	Week 2	5%, 95%	658.5, 6181.5	672.1, 4260.1	0.0545
		N	64	56	
		MEAN, GEO MEAN	2741.6, 2193.0	2216.5, 1754.9	
		SD, SE	1918.92, 239.86	1874.30, 250.46	
		MEDIAN	2101.6	1750.7	
	Week 3	MIN, MAX	601.6, 9111.0	617.9, 11029.7	0.2053
		5%, 95%	734.4, 7363.1	704.6, 5517.6	
		N	60	50	
		MEAN, GEO MEAN	2356.2, 1992.0	2005.3, 1717.4	
		SD, SE	1466.87, 189.37	1148.15, 162.37	
	Overall	MEDIAN	1878.0	1718.2	0.0067
		MIN, MAX	639.6, 7794.0	617.9, 5159.8	
		5%, 95%	716.8, 5361.8	710.0, 4246.6	
		N	183	161	
		MEAN, GEO MEAN	2469.2, 2015.7	2016.5, 1672.0	
		SD, SE	1740.37, 128.65	1424.98, 112.30	
		MEDIAN	1951.2	1634.1	
		MIN, MAX	601.6, 9853.6	617.9, 11029.7	
		5%, 95%	693.8, 5875.3	693.8, 4336.0	

TABLE 14.2.1-2  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
(Page 3 of 7)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value*
11-Dehydrothromboxane B <sub>2</sub> (pg/24hr)	Week 1	N	59	55	0.0064
		MEAN, GEO MEAN	1357797.915, 1184665.613	1007599.000, 934075.235	
		SD, SE	730785.0879, 95140.1147	389305.9122, 52493.9985	
		MEDIAN	1308300.000	934150.000	
		MIN, MAX	393240.000, 4272300.000	438200.000, 2065650.000	
	Week 2	5%, 95%	448200.0, 2908320.0	482400.0, 1782000.0	0.0918
		N	64	56	
		MEAN, GEO MEAN	1386884.844, 1229501.044	1159310.268, 1046352.727	
		SD, SE	682544.6144, 85318.0768	584007.4679, 78041.2806	
		MEDIAN	1213220.000	1120780.000	
	Week 3	MIN, MAX	388500.000, 3025800.000	382800.000, 3993300.000	0.1937
		5%, 95%	530660.0, 2841768.0	465365.0, 2037840.0	
		N	60	50	
		MEAN, GEO MEAN	1587630.817, 1315000.013	1236106.060, 1142519.707	
		SD, SE	1227749.8372, 158501.8224	479263.3232, 67778.0692	
	Overall	MEDIAN	1274000.000	1237080.000	0.0007
		MIN, MAX	379376.000, 8904654.000	367080.000, 2522260.000	
		5%, 95%	480220.0, 2839780.0	539110.0, 2000300.0	
		N	183	161	
		MEAN, GEO MEAN	1443325.443, 1241938.965	1131333.062, 1034419.394	
		SD, SE	911296.7973, 67364.9977	497697.7132, 39224.0747	
		MEDIAN	1272642.000	1083560.000	
		MIN, MAX	379376.000, 8904654.000	367080.000, 3993300.000	
		5%, 95%	476580.0, 2841768.0	472650.0, 1926400.0	



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TABLE 14.2.1-2  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
 (Page 4 of 7)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
11-Dehydrothromboxane B <sub>2</sub> (pmol/24hr)	Week 1	N	59	55	0.0064
		MEAN, GEO MEAN	3679.632, 3210.444	2730.593, 2531.344	
		SD, SE	1980.4276, 257.8297	1055.0191, 142.2587	
		MEDIAN	3545.493	2531.547	
		MIN, MAX	1065.680, 11577.933	1187.522, 5597.912	
	Week 2	5%, 95%	1214.6, 7881.5	1307.3, 4829.2	0.0918
		N	64	56	
		MEAN, GEO MEAN	3758.458, 3331.948	3141.731, 2835.616	
		SD, SE	1849.6959, 231.2120	1582.6602, 211.4919	
		MEDIAN	3287.826	3037.314	
	Week 3	MIN, MAX	1052.835, 8199.918	1037.388, 10821.843	0.1937
		5%, 95%	1438.1, 7701.2	1261.1, 5522.5	
		N	60	50	
		MEAN, GEO MEAN	4302.480, 3563.650	3349.847, 3096.228	
		SD, SE	3327.2020, 429.5399	1298.8037, 183.6786	
	Overall	MEDIAN	3452.540	3352.487	0.0007
		MIN, MAX	1028.109, 24131.612	994.787, 6835.325	
		5%, 95%	1301.4, 7695.8	1461.0, 5420.8	
		N	183	161	
		MEAN, GEO MEAN	3911.412, 3365.655	3065.913, 2803.277	
		SD, SE	2469.6143, 182.5591	1348.7608, 106.2972	
		MEDIAN	3448.860	2936.448	
		MIN, MAX	1028.109, 24131.612	994.787, 10821.843	
		5%, 95%	1291.5, 7701.2	1280.9, 5220.5	

**G**

PM3006635379

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TABLE 14.2.1-2  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
 (Page 11 of 2)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
8-epi-prostaglandin F <sub>2α</sub> (pg/mg Creatinin)	Week 1	N	65	63	0.0000
		MEAN, GEO MEAN	1850.916, 1672.752	1100.820, 1046.146	
		SD, SE	876.8792, 108.7635	345.5869, 43.5399	
		MEDIAN	1711.133	1059.006	
		MIN, MAX 5%, 95%	628.533, 5774.566 741.2, 3277.1	337.011, 2047.308 634.1, 1828.8	
	Week 2	N	69	67	0.0000
		MEAN, GEO MEAN	2006.274, 1774.855	1172.227, 1115.110	
		SD, SE	1089.3046, 131.1369	387.4002, 47.3285	
		MEDIAN	1581.213	1098.068	
		MIN, MAX 5%, 95%	649.573, 6076.687 854.9, 4021.2	421.429, 2750.000 715.2, 1814.7	
	Week 3	N	66	61	0.0000
		MEAN, GEO MEAN	1919.242, 1759.908	1145.211, 1084.428	
		SD, SE	819.5982, 100.8856	374.0712, 47.8949	
		MEDIAN	1732.134	1102.506	
		MIN, MAX 5%, 95%	675.556, 4511.384 836.2, 3592.3	514.825, 1950.000 629.4, 1725.5	
	Overall	N	200	191	0.0000
		MEAN, GEO MEAN	1927.062, 1736.153	1140.046, 1082.188	
		SD, SE	936.0869, 66.1913	369.0214, 26.7015	
		MEDIAN	1710.627	1088.452	
		MIN, MAX 5%, 95%	628.533, 6076.687 813.5, 3650.9	337.011, 2750.000 642.5, 1808.2	

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TABLE 14.2.1-2  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
 (Page 12 of 7)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value*
8-epi-prostaglandin F <sub>2α</sub> (pmol/mg Creatin)	Week 1	N	65	63	0.0000
		MEAN, GEO MEAN	5.220, 4.717	3.104, 2.950	
		SD, SE	2.4728, 0.3067	0.9746, 0.1228	
		MEDIAN	4.825	2.986	
		MIN, MAX	1.772, 16.284	0.950, 5.773	
	Week 2	5%, 95%	2.1, 9.2	1.8, 5.2	0.0000
		N	69	67	
		MEAN, GEO MEAN	5.658, 5.005	3.306, 3.145	
		SD, SE	3.0719, 0.3698	1.0924, 0.1335	
		MEDIAN	4.459	3.097	
	Week 3	MIN, MAX	1.832, 17.136	1.188, 7.755	0.0000
		5%, 95%	2.4, 11.3	2.0, 5.1	
		N	66	61	
		MEAN, GEO MEAN	5.412, 4.963	3.229, 3.058	
		SD, SE	2.3112, 0.2845	1.0549, 0.1351	
	Overall	MEDIAN	4.885	3.109	0.0000
		MIN, MAX	1.905, 12.722	1.452, 5.499	
		5%, 95%	2.4, 10.1	1.8, 4.9	
		N	200	191	
		MEAN, GEO MEAN	5.434, 4.896	3.215, 3.052	
		SD, SE	2.6398, 0.1867	1.0406, 0.0753	
		MEDIAN	4.824	3.069	
		MIN, MAX	1.772, 17.136	0.950, 7.755	
		5%, 95%	2.3, 10.3	1.8, 5.1	

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TABLE 14.2.1-2  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
8-epi-prostaglandin F <sub>2α</sub> (pg/mL)	Week 1	N	65	63	0.0083
		MEAN, GEO MEAN	1605.1, 1208.4	1020.2, 846.1	
		SD, SE	1340.18, 166.23	696.70, 87.78	
		MEDIAN	1064.0	769.0	
		MIN, MAX	316.0, 5950.0	280.0, 3363.0	
	Week 2	5%, 95%	397.0, 5050.0	359.0, 2638.0	0.0001
		N	69	67	
		MEAN, GEO MEAN	1910.4, 1472.5	1110.4, 883.0	
		SD, SE	1398.10, 168.31	784.68, 95.86	
		MEDIAN	1616.0	739.0	
	Week 3	MIN, MAX	359.0, 7271.0	270.0, 3297.0	0.0001
		5%, 95%	417.0, 3983.0	344.0, 2791.0	
		N	66	61	
		MEAN, GEO MEAN	1546.1, 1270.4	975.2, 818.3	
		SD, SE	1045.25, 128.66	651.06, 83.36	
	Overall	MEDIAN	1187.0	757.0	0.0000
		MIN, MAX	349.0, 4779.0	275.0, 3143.0	
		5%, 95%	463.0, 3938.0	390.0, 2422.0	
		N	200	191	
		MEAN, GEO MEAN	1691.0, 1315.2	1037.5, 849.7	
		SD, SE	1276.12, 90.24	713.68, 51.64	
		MEDIAN	1207.5	763.0	
		MIN, MAX	316.0, 7271.0	270.0, 3363.0	
		5%, 95%	413.0, 4149.0	359.0, 2638.0	

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TABLE 14.2.1-2  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
8-epi-prostaglandin F <sub>2α</sub> (pmol/L)	Week 1	N	65	63	0.0083
		MEAN, GEO MEAN	4526.5, 3407.6	2876.9, 2385.9	
		SD, SE	3779.29, 468.76	1964.71, 247.53	
		MEDIAN	3000.5	2168.6	
		MIN, MAX	891.1, 16779.0	789.6, 9483.7	
	Week 2	5%, 95%	1119.5, 14241.0	1012.4, 7439.2	0.0001
		N	69	67	
		MEAN, GEO MEAN	5387.5, 4152.6	3131.2, 2490.2	
		SD, SE	3942.64, 474.64	2212.78, 270.33	
		MEDIAN	4557.1	2084.0	
	Week 3	MIN, MAX	1012.4, 20504.2	761.4, 9297.5	0.0001
		5%, 95%	1175.9, 11232.1	970.1, 7870.6	
		N	66	61	
		MEAN, GEO MEAN	4360.1, 3582.4	2750.1, 2307.5	
		SD, SE	2947.60, 362.82	1835.99, 235.07	
	Overall	MEDIAN	3347.4	2134.7	0.0000
		MIN, MAX	984.2, 13476.8	775.5, 8863.3	
		5%, 95%	1305.7, 11105.2	1099.8, 6830.0	
		N	200	191	
		MEAN, GEO MEAN	4768.6, 3708.9	2925.6, 2396.3	
		SD, SE	3598.67, 254.46	2012.59, 145.63	
		MEDIAN	3405.2	2151.7	
		MIN, MAX	891.1, 20504.2	761.4, 9483.7	
		5%, 95%	1164.7, 11700.2	1012.4, 7439.2	

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TABLE 14.2.1-2  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
8-epi-prostaglandin F <sub>2α</sub> (pg/24hr)	Week 1	N	65	63	0.0000
		MEAN, GEO MEAN	2502329.615, 2134883.086	1599335.921, 1448451.638	
		SD, SE	1374713.9941, 170512.2854	746231.0968, 94016.2811	
		MEDIAN	2268160.000	1470600.000	
		MIN, MAX	345390.000, 6602325.000	403200.000, 4204250.000	
	Week 2	5%, 95%	720510.0, 4646400.0	693220.0, 3129140.0	0.0000
		N	69	67	
		MEAN, GEO MEAN	2615423.536, 2305044.057	1677899.179, 1531280.985	
		SD, SE	1321662.0149, 159109.4092	775489.7293, 94741.1493	
		MEDIAN	2333120.000	1430580.000	
	Week 3	MIN, MAX	702900.000, 7718500.000	499730.000, 4601300.000	0.0000
		5%, 95%	855000.0, 4944280.0	879360.0, 3133645.0	
		N	66	61	
		MEAN, GEO MEAN	2960816.576, 2349204.304	1699148.148, 1532621.565	
		SD, SE	2992871.4272, 368397.0063	810596.3382, 103786.2260	
	Overall	MEDIAN	2527070.000	1484400.000	0.0000
		MIN, MAX	567750.000, 24022683.000	580650.000, 3757600.000	
		5%, 95%	728420.0, 5346600.0	754725.0, 3443440.0	
		N	200	191	
		MEAN, GEO MEAN	2692647.715, 2262428.046	1658771.963, 1503869.889	
		SD, SE	2041610.8409, 144363.6870	774553.3047, 56044.7102	
		MEDIAN	2346100.000	1445840.000	
		MIN, MAX	345390.000, 24022683.000	403200.000, 4601300.000	
		5%, 95%	732310.0, 5162100.0	775520.0, 3270240.0	

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TABLE 14.2.1-2  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value*
8-epi-prostaglandin F <sub>2α</sub> (pmol/24hr)	Week 1	N	65	63	0.0000
		MEAN, GEO MEAN	7056.570, 6020.370	4510.127, 4084.634	
		SD, SE	3876.6935, 480.8446	2104.3717, 265.1259	
		MEDIAN	6396.211	4147.092	
		MIN, MAX	974.000, 18618.557	1137.024, 11855.985	
	Week 2	5%, 95%	2031.8, 13102.8	1954.9, 8824.2	0.0000
		N	69	67	
		MEAN, GEO MEAN	7375.494, 6500.224	4731.676, 4318.212	
		SD, SE	3727.0869, 448.6885	2186.8810, 267.1700	
		MEDIAN	6579.398	4034.236	
	Week 3	MIN, MAX	1982.178, 21766.170	1409.239, 12975.666	0.0000
		5%, 95%	2411.1, 13942.9	2479.8, 8836.9	
		N	66	61	
		MEAN, GEO MEAN	8349.503, 6624.756	4791.598, 4321.993	
		SD, SE	8439.8974, 1038.8796	2285.8817, 292.6772	
	Overall	MEDIAN	7126.338	4186.008	0.0000
		MIN, MAX	1601.055, 67743.966	1637.433, 10596.432	
		5%, 95%	2054.1, 15077.4	2128.3, 9710.5	
		N	200	191	
		MEAN, GEO MEAN	7593.267, 6380.047	4677.737, 4240.913	
		SD, SE	5757.3426, 407.1056	2184.2403, 158.0461	
		MEDIAN	6616.002	4077.269	
		MIN, MAX	974.000, 67743.966	1137.024, 12975.666	
		5%, 95%	2065.1, 14557.1	2187.0, 9222.1	



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TABLE 14.2.1-2  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
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Biomarker		Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
Malondialdehyde	(umol/mg Creatin)	Week 1	N	67	68	0.3349
			MEAN, GEO MEAN	0.002, 0.002	0.002, 0.002	
			SD, SE	0.0011, 0.0001	0.0012, 0.0001	
			MEDIAN	0.002	0.001	
			MIN, MAX	0.001, 0.006	0.001, 0.009	
			5%, 95%	0.0, 0.0	0.0, 0.0	
		Week 2	N	68	67	0.2983
			MEAN, GEO MEAN	0.002, 0.001	0.002, 0.002	
			SD, SE	0.0007, 0.0001	0.0008, 0.0001	
			MEDIAN	0.002	0.002	
			MIN, MAX	0.001, 0.004	0.001, 0.004	
			5%, 95%	0.0, 0.0	0.0, 0.0	
		Week 3	N	67	67	0.1271
			MEAN, GEO MEAN	0.002, 0.002	0.002, 0.001	
			SD, SE	0.0008, 0.0001	0.0009, 0.0001	
			MEDIAN	0.002	0.001	
			MIN, MAX	0.001, 0.006	0.001, 0.006	
			5%, 95%	0.0, 0.0	0.0, 0.0	
		Overall	N	202	202	0.4091
			MEAN, GEO MEAN	0.002, 0.002	0.002, 0.002	
			SD, SE	0.0009, 0.0001	0.0010, 0.0001	
			MEDIAN	0.002	0.002	
			MIN, MAX	0.001, 0.006	0.001, 0.009	
			5%, 95%	0.0, 0.0	0.0, 0.0	

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TABLE 14.2.1-2  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
 (Page 14 of ?)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
Malondialdehyde (umol/24hr)	Week 1	N	67	68	0.9649
		MEAN, GEO MEAN	2.490, 2.181	2.478, 2.244	
		SD, SE	1.4134, 0.1727	1.5208, 0.1844	
		MEDIAN	2.139	2.263	
		MIN, MAX	0.444, 8.554	1.220, 12.527	
		5%, 95%	1.0, 4.9	1.3, 4.5	
	Week 2	N	68	67	0.7816
		MEAN, GEO MEAN	2.255, 2.113	2.447, 2.255	
		SD, SE	0.8269, 0.1003	1.0949, 0.1338	
		MEDIAN	2.202	2.030	
		MIN, MAX	0.756, 5.132	1.152, 6.535	
		5%, 95%	1.2, 3.8	1.4, 4.7	
	Week 3	N	67	67	0.6531
		MEAN, GEO MEAN	2.552, 2.124	2.317, 2.092	
		SD, SE	2.0332, 0.2484	1.2997, 0.1588	
		MEDIAN	2.116	1.959	
		MIN, MAX	0.383, 14.912	0.794, 9.953	
		5%, 95%	0.8, 6.5	1.2, 4.3	
	Overall	N	202	202	0.9806
		MEAN, GEO MEAN	2.432, 2.139	2.414, 2.196	
		SD, SE	1.5026, 0.1057	1.3131, 0.0924	
		MEDIAN	2.159	2.078	
		MIN, MAX	0.383, 14.912	0.794, 12.527	
		5%, 95%	1.0, 4.8	1.3, 4.4	

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TABLE 14.2.1-2  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
Malondialdehyde ( $\mu\text{mol/L}$ )	Week 1	N	67	68	0.4130
		MEAN, GEO MEAN	1.54, 1.27	1.60, 1.37	
		SD, SE	1.106, 0.135	0.974, 0.118	
		MEDIAN	1.18	1.21	
		MIN, MAX	0.40, 6.11	0.48, 5.35	
		5%, 95%	0.5, 4.0	0.6, 3.7	
	Week 2	N	68	67	0.6346
		MEAN, GEO MEAN	1.58, 1.35	1.50, 1.30	
		SD, SE	0.887, 0.108	0.834, 0.102	
		MEDIAN	1.38	1.29	
		MIN, MAX	0.41, 4.31	0.49, 3.89	
		5%, 95%	0.6, 3.6	0.6, 3.2	
	Week 3	N	67	67	0.3794
		MEAN, GEO MEAN	1.38, 1.19	1.32, 1.12	
		SD, SE	0.898, 0.110	0.890, 0.109	
		MEDIAN	1.20	1.11	
		MIN, MAX	0.40, 6.30	0.40, 6.26	
		5%, 95%	0.5, 2.8	0.5, 2.5	
	Overall	N	202	202	0.8459
		MEAN, GEO MEAN	1.50, 1.27	1.47, 1.26	
		SD, SE	0.967, 0.068	0.905, 0.064	
		MEDIAN	1.21	1.18	
		MIN, MAX	0.40, 6.30	0.40, 6.26	
		5%, 95%	0.5, 3.5	0.6, 3.1	

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TABLE 14.2.1-2  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
OF 24-HOUR URINE BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
(Page 16 of ?)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
24-hr Urine Creatinine (mg/24hr)	Week 1	N	69	68	0.2965
		MEAN, GEO MEAN	1377.160, 1270.735	1478.498, 1402.911	
		SD, SE	519.1772, 62.5016	483.0673, 58.5805	
		MEDIAN	1378.980	1359.550	
		MIN, MAX 5%, 95%	332.160, 3002.125 614.8, 2205.0	500.800, 2973.880 845.6, 2386.0	
	Week 2	N	69	68	0.4656
		MEAN, GEO MEAN	1372.680, 1298.723	1434.754, 1363.027	
		SD, SE	457.4009, 55.0646	469.6448, 56.9528	
		MEDIAN	1316.480	1385.170	
		MIN, MAX 5%, 95%	505.300, 2577.710 726.3, 2201.8	735.150, 2728.350 803.7, 2238.5	
	Week 3	N	68	67	0.2684
		MEAN, GEO MEAN	1572.331, 1320.802	1502.281, 1396.406	
		SD, SE	1665.3258, 201.9504	567.5461, 69.3368	
		MEDIAN	1341.625	1396.050	
		MIN, MAX 5%, 95%	379.500, 14230.404 586.3, 2331.0	410.000, 3032.400 715.4, 2760.6	
	Overall	N	206	203	0.0862
		MEAN, GEO MEAN	1440.085, 1296.475	1471.694, 1387.293	
		SD, SE	1036.2772, 72.2009	506.5435, 35.5524	
		MEDIAN	1327.200	1387.200	
		MIN, MAX 5%, 95%	332.160, 14230.404 621.8, 2253.6	410.000, 3032.400 792.0, 2386.0	

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TABLE 14.2.1-1  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL.  
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Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
HDL-Cholesterol (mg/dL)	Week 1	N	69	68	0.0010
		MEAN, GEO MEAN	47, 45	55, 53	
		SD, SE	11.1, 1.3	14.8, 1.8	
		MEDIAN	46	53	
		MIN, MAX	23, 81	26, 96	
	Week 3	5%, 95%	30.0, 62.0	34.0, 79.0	0.0007
		N	68	67	
		MEAN, GEO MEAN	46, 45	54, 52	
		SD, SE	12.0, 1.5	13.6, 1.7	
		MEDIAN	44	52	
	Week 6	MIN, MAX	24, 79	31, 86	0.0001
		5%, 95%	31.0, 64.0	33.0, 81.0	
		N	68	67	
		MEAN, GEO MEAN	45, 44	54, 52	
		SD, SE	10.1, 1.2	13.0, 1.6	
	Overall	MEDIAN	46	54	0.0000
		MIN, MAX	28, 82	29, 89	
		5%, 95%	30.0, 61.0	37.0, 78.0	
		N	205	202	
		MEAN, GEO MEAN	46, 45	54, 53	
		SD, SE	11.1, 0.8	13.8, 1.0	
		MEDIAN	45	53	
		MIN, MAX	23, 82	26, 96	
		5%, 95%	30.0, 63.0	34.0, 79.0	



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TABLE 14.2.3-1  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER  
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
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Biomarker	Timepoint	Statistic	Smokers			Non-Smokers		
			Male	Female	P-value*	Male	Female	P-value*
LDL-Cholesterol (mg/dL)	Week 1	N	30	39	0.2098	32	36	0.0001
		MEAN, GEO MEAN	45, 44	48, 46		47, 46	61, 60	
		SD, SE	9.8, 1.8	12.0, 1.9		12.1, 2.1	14.0, 2.3	
		MEDIAN	44	50		46	60	
		MIN, MAX	30, 62	23, 81		26, 77	36, 96	
		5%, 95%	30.0, 62.0	29.0, 62.0		27.0, 66.0	41.0, 92.0	
	Week 3	N	30	38	0.1921	31	36	0.0001
		MEAN, GEO MEAN	44, 43	48, 46		47, 46	60, 59	
		SD, SE	10.0, 1.8	13.3, 2.2		11.6, 2.1	12.2, 2.0	
		MEDIAN	44	48		45	58	
		MIN, MAX	31, 63	24, 79		31, 77	40, 86	
		5%, 95%	31.0, 63.0	25.0, 75.0		32.0, 73.0	40.0, 85.0	
	Week 6	N	30	38	0.2006	31	36	0.0001
		MEAN, GEO MEAN	44, 43	47, 45		47, 46	60, 59	
		SD, SE	9.0, 1.6	10.9, 1.8		11.1, 2.0	11.9, 2.0	
		MEDIAN	43	47		44	57	
		MIN, MAX	30, 65	28, 82		29, 74	41, 89	
		5%, 95%	31.0, 61.0	29.0, 61.0		33.0, 71.0	45.0, 81.0	
	Overall	N	90	115	0.0346	94	108	0.0000
		MEAN, GEO MEAN	44, 43	48, 46		47, 46	60, 59	
		SD, SE	9.5, 1.0	12.0, 1.1		11.5, 1.2	12.6, 1.2	
		MEDIAN	44	47		45	58	
		MIN, MAX	30, 65	23, 82		26, 77	36, 96	
		5%, 95%	31.0, 62.0	29.0, 64.0		32.0, 71.0	43.0, 85.0	

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TABLE 14.2.1-1  
 STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
 OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
 (Page 2 of 7)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
LDL-Cholesterol (mg/dL)	Week 1	N	67	66	0.0532
		MEAN, GEO MEAN	121, 117	112, 108	
		SD, SE	31.7, 3.9	29.6, 3.6	
		MEDIAN	121	109	
		MIN, MAX	55, 231	56, 200	
		5%, 95%	76.0, 172.0	75.0, 173.0	
	Week 3	N	67	67	0.0457
		MEAN, GEO MEAN	116, 113	106, 102	
		SD, SE	28.5, 3.5	30.6, 3.7	
		MEDIAN	119	100	
		MIN, MAX	60, 199	36, 190	
		5%, 95%	69.0, 164.0	60.0, 153.0	
	Week 6	N	68	67	0.1972
		MEAN, GEO MEAN	118, 114	111, 106	
		SD, SE	32.0, 3.9	34.4, 4.2	
		MEDIAN	120	109	
		MIN, MAX	50, 227	29, 214	
		5%, 95%	73.0, 163.0	61.0, 168.0	
	Overall	N	202	200	0.0025
		MEAN, GEO MEAN	119, 115	110, 105	
		SD, SE	30.7, 2.2	31.6, 2.2	
		MEDIAN	120	107	
		MIN, MAX	50, 231	29, 214	
		5%, 95%	72.0, 170.0	61.5, 166.5	

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TABLE 14.2.3-1  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER  
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
(Page 2 of 9)

Biomarker	Timepoint	Statistic	Smokers		P-value <sup>a</sup>	Non-Smokers		P-value <sup>a</sup>
			Male	Female		Male	Female	
LDL-Cholesterol (mg/dL)	Week 1	N	29	38	0.5226	30	36	0.2463
		MEAN, GEO MEAN	123, 118	120, 116		107, 104	116, 112	
		SD, SE	30.5, 5.7	32.9, 5.3		28.0, 5.1	30.8, 5.1	
		MEDIAN	122	121		101	112	
		MIN, MAX	55, 175	57, 231		56, 173	56, 200	
		5%, 95%	61.0, 170.0	76.0, 181.0		62.0, 157.0	75.0, 185.0	
	Week 3	N	30	37	0.0898	31	36	0.1908
		MEAN, GEO MEAN	122, 119	112, 108		102, 96	110, 107	
		SD, SE	27.5, 5.0	29.0, 4.8		35.1, 6.3	26.0, 4.3	
		MEDIAN	124	109		97	113	
		MIN, MAX	66, 174	60, 199		36, 190	60, 164	
		5%, 95%	72.0, 164.0	64.0, 173.0		55.0, 170.0	62.0, 153.0	
	Week 6	N	30	38	0.4043	31	36	0.6017
		MEAN, GEO MEAN	120, 116	117, 113		109, 101	114, 110	
		SD, SE	30.4, 5.5	33.6, 5.5		38.8, 7.0	30.5, 5.1	
		MEDIAN	124	114		109	108	
		MIN, MAX	58, 187	50, 227		29, 214	64, 185	
		5%, 95%	73.0, 163.0	73.0, 185.0		52.0, 165.0	72.0, 185.0	
	Overall	N	89	113	0.0781	92	108	0.0884
		MEAN, GEO MEAN	121, 118	116, 112		106, 100	113, 109	
		SD, SE	29.2, 3.1	31.8, 3.0		34.1, 3.6	29.0, 2.8	
		MEDIAN	123	116		100	112	
		MIN, MAX	55, 187	50, 231		29, 214	56, 200	
		5%, 95%	72.0, 168.0	70.0, 173.0		56.0, 163.0	71.0, 168.0	

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TABLE 14.2.1-1  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
(Page 3 of 7)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value*
Fibrinogen (mg/dL)	Week 1	N MEAN, GEO MEAN SD, SE MIN, MAX 5%, 95%	69 299, 292 72.5, 8.7 290 175, 573 210.0, 444.0	68 257, 247 72.4, 8.8 259 117, 474 153.0, 383.0	0.0006
	Week 3	N MEAN, GEO MEAN SD, SE MIN, MAX 5%, 95%	67 290, 277 91.7, 11.2 121, 634 155.0, 465.0	67 252, 240 79.3, 9.7 243 111, 509 124.0, 405.0	0.0083
	Week 6	N MEAN, GEO MEAN SD, SE MIN, MAX 5%, 95%	66 280, 269 80.1, 9.9 153, 483 168.0, 444.0	65 253, 245 63.1, 7.8 245 123, 394 146.0, 354.0	0.0876
	Overall	N MEAN, GEO MEAN SD, SE MIN, MAX 5%, 95%	202 290, 279 81.7, 5.7 121, 634 175.0, 444.0	200 254, 244 71.6, 5.1 111, 509 140.5, 383.0	0.0000

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TABLE 14.2.3-1  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER  
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
(Page 3 of 7)

Biomarker	Timepoint	Statistic	Smokers		P-value <sup>a</sup>	Non-Smokers		P-value <sup>a</sup>
			Male	Female		Male	Female	
Fibrinogen (mg/dL)	Week 1	N	30	39	0.0000	32	36	0.0037
		MEAN, GEO MEAN	261, 257	329, 322		229, 223	282, 271	
		SD, SE	47.9, 8.7	75.1, 12.0		53.2, 9.4	78.6, 13.1	
		MEDIAN	260	308		221	278	
		MIN, MAX	175, 373	234, 573		132, 354	117, 474	
		5%, 95%	186.0, 363.0	245.0, 550.0		150.0, 302.0	166.0, 434.0	
	Week 3	N	30	37	0.1615	31	36	0.0160
		MEAN, GEO MEAN	271, 261	306, 291		226, 216	275, 262	
		SD, SE	72.6, 13.3	102.8, 16.9		62.4, 11.2	85.9, 14.3	
		MEDIAN	269	300		234	273	
		MIN, MAX	121, 465	144, 634		111, 354	111, 509	
		5%, 95%	155.0, 383.0	148.0, 573.0		116.0, 328.0	153.0, 449.0	
	Week 6	N	30	36	0.0008	30	35	0.0014
		MEAN, GEO MEAN	242, 236	312, 300		226, 220	276, 268	
		SD, SE	54.7, 10.0	84.7, 14.1		49.8, 9.1	64.5, 10.9	
		MEDIAN	244	302		225	279	
		MIN, MAX	157, 394	153, 483		123, 335	124, 394	
		5%, 95%	166.0, 329.0	191.0, 458.0		133.0, 293.0	160.0, 394.0	
	Overall	N	90	112	0.0000	93	107	0.0000
		MEAN, GEO MEAN	258, 251	316, 304		227, 220	278, 267	
		SD, SE	59.9, 6.3	87.8, 8.3		54.8, 5.7	76.3, 7.4	
		MEDIAN	254	306		229	274	
		MIN, MAX	121, 465	144, 634		111, 354	111, 509	
		5%, 95%	168.0, 363.0	191.0, 483.0		132.0, 322.0	160.0, 405.0	

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TABLE 14.2.1-1  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS  
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
(Page 4 of 7)

Biomarker	Timepoint	Statistic	Smokers	Non-Smokers	P-value <sup>a</sup>
C-Reactive Protein (mg/dL)	Week 1	N	62	66	0.0166
		MEAN, GEO MEAN	0.384, 0.208	0.308, 0.131	
		SD, SE	0.4771, 0.0606	0.7115, 0.0876	
		MEDIAN	0.199	0.126	
		MIN, MAX	0.021, 2.790	0.020, 5.500	
		5%, 95%	0.0, 1.3	0.0, 0.9	
	Week 3	N	63	65	0.0111
		MEAN, GEO MEAN	0.370, 0.193	0.225, 0.117	
		SD, SE	0.4639, 0.0584	0.3594, 0.0446	
		MEDIAN	0.218	0.108	
		MIN, MAX	0.023, 1.900	0.022, 2.200	
		5%, 95%	0.0, 1.5	0.0, 0.9	
	Week 6	N	63	65	0.0335
		MEAN, GEO MEAN	0.373, 0.196	0.323, 0.131	
		SD, SE	0.4707, 0.0593	0.6399, 0.0794	
		MEDIAN	0.213	0.116	
		MIN, MAX	0.022, 2.480	0.020, 3.560	
		5%, 95%	0.0, 1.2	0.0, 1.6	
	Overall	N	188	196	0.0000
		MEAN, GEO MEAN	0.375, 0.199	0.285, 0.126	
		SD, SE	0.4681, 0.0341	0.5894, 0.0421	
		MEDIAN	0.213	0.113	
		MIN, MAX	0.021, 2.790	0.020, 5.500	
		5%, 95%	0.0, 1.5	0.0, 1.0	

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TABLE 14.2.3-1  
STATISTICAL COMPARISON BETWEEN SMOKERS AND NON-SMOKERS BY GENDER  
OF BLOOD AND/OR PLASMA BIOMARKERS OF EFFECT BY TIMEPOINT AND OVERALL  
(Page 4 of 7)

Biomarker	Timepoint	Statistic	Smokers		P-value*	Non-Smokers		P-value*
			Male	Female		Male	Female	
C-Reactive Protein (mg/dL)	Week 1	N	26	36	0.0060	31	35	0.0006
		MEAN, GEO MEAN	0.223, 0.130	0.500, 0.293		0.146, 0.079	0.451, 0.206	
		SD, SE	0.3022, 0.0593	0.5462, 0.0910		0.2579, 0.0463	0.9296, 0.1571	
		MEDIAN	0.120	0.304		0.071	0.172	
		MIN, MAX	0.021, 1.530	0.022, 2.790		0.020, 1.330	0.028, 5.500	
		5%, 95%	0.0, 0.5	0.0, 1.4		0.0, 0.7	0.0, 1.4	
	Week 3	N	26	37	0.1990	31	34	0.0001
		MEAN, GEO MEAN	0.339, 0.156	0.391, 0.225		0.088, 0.068	0.349, 0.192	
		SD, SE	0.5218, 0.1023	0.4248, 0.0698		0.0781, 0.0140	0.4599, 0.0789	
		MEDIAN	0.149	0.259		0.059	0.147	
		MIN, MAX	0.023, 1.900	0.027, 1.630		0.022, 0.425	0.027, 2.200	
		5%, 95%	0.0, 1.7	0.0, 1.5		0.0, 0.2	0.0, 1.5	
	Week 6	N	27	36	0.0172	29	36	0.0027
		MEAN, GEO MEAN	0.278, 0.135	0.445, 0.259		0.256, 0.086	0.377, 0.185	
		SD, SE	0.4324, 0.0832	0.4912, 0.0819		0.6543, 0.1215	0.6320, 0.1053	
		MEDIAN	0.157	0.329		0.065	0.164	
		MIN, MAX	0.022, 1.940	0.032, 2.480		0.020, 2.980	0.026, 3.560	
		5%, 95%	0.0, 1.2	0.0, 1.5		0.0, 2.2	0.0, 1.6	
	Overall	N	79	109	0.0002	91	105	0.0000
		MEAN, GEO MEAN	0.280, 0.140	0.445, 0.257		0.161, 0.077	0.393, 0.194	
		SD, SE	0.4256, 0.0479	0.4869, 0.0466		0.4027, 0.0422	0.6971, 0.0680	
		MEDIAN	0.125	0.285		0.065	0.166	
		MIN, MAX	0.021, 1.940	0.022, 2.790		0.020, 2.980	0.026, 5.500	
		5%, 95%	0.0, 1.5	0.0, 1.4		0.0, 0.4	0.0, 1.4	